



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

21 DEC 2004

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| Applicant's or agent's file reference P 667 PC00 | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/DK 03/00424 | International filing date (day/month/year) 23.06.2003 | Priority date (day/month/year) 21.06.2002 | |
| International Patent Classification (IPC) or both national classification and IPC A23L1/307 | | | |
| Applicant DANSK DROGE AS et al. | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 6 sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | | |
| Date of submission of the demand 13.01.2004 | | Date of completion of this report 12.08.2004 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized Officer Korb, M Telephone No. +49 89 2399-8639  | |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00424**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-19 as originally filed

Claims, Numbers

1-41 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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EXAMINATION REPORT**

International application No. PCT/DK 03/00424

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-9, 16-41

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-9, 16-41

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------------|
| Novelty (N) | Yes: Claims | 13, 15 |
| | No: Claims | 10,11,12,14 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 10-15 |
| Industrial applicability (IA) | Yes: Claims | 10-15 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item I

Basis of the report

This International Preliminary Report is based on the claims 10 to 15 as originally filed.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No International Preliminary Report is established for claims 1-9, 16-41 as originally filed (see the International Search Report). No preliminary examination is carried out on the amended claims 1-36 filed with the applicant's letter dated 25.05.2004 due to matter which has not been searched (Rule 66.1(e) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

D1: US-A-4 548 937 (STANKO RONALD T) 22 October 1985 (1985-10-22)

2. D1(cf. col.2, l24-29 and l.31-44) discloses diets for preventing body fat deposition in mammals comprising protein, fat and carbohydrate with addition of pyruvate and/or dihydroxyacetone. D1 discloses the addition of 124 g pyruvate per 1000g diet. Hence, the low-energy-diet according to claims 10, 11, 12 and 14 is not considered novel over D1 (Art. 33(2) PCT).

3. Claim 13 which defines dihydroxy acetone phosphate in an amount of from 5g to 15 g is not disclosed in D1 and appears to be novel over D1 (Art. 33(2) PCT).
Claim 15 defines the pyruvate in the form of sodium pyruvate and/or calcium pyruvate which is not expressis verbis mentioned in D1 and appears therefore to be novel over D1 (Art. 33(2) PCT).

4. Nevertheless, the solution proposed in claims 13 and 14 of the present application

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REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

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cannot be considered as involving an inventive step (Article 33(3) PCT) since the skilled person having the knowledge of D1 would regard it a normal design procedure.

5. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

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Low-energy-diet

Amended claims filed in response to First Written Opinion

- 5 1. A low-energy-diet comprising as ingredients sources of
- protein in an amount of from 50 g to 80 g per day,
carbohydrate in an amount of from 70 g to 120 g per day,
fat 5-20 g per day, including at least 3 g middle chain triglycerides per day,
- 10 and optionally minerals and pH-regulating agents, wherein one or more of the
ingredient(s) has effect on at least two of the following mechanisms
- the basal metabolic rate, and/or
- 15 the protein metabolism, and /or
the energy expenditure,
- when the low-energy-diet is administered as the main or sole nutrition, and
wherein the diet has an energy content in the range of from 600 kcal/d to 1200
- 20 kcal/d.
2. The low-energy-diet according to claim 2, wherein the diet has an energy con-
tent of approximately 800 kcal/d.
- 25 3. The low-energy-diet according to any of the preceding claims, wherein the
source of protein is selected from casein, pork protein, and/or soy protein
4. The low-energy-diet according to claim 3, wherein at least a portion of the
source of protein is soy protein.
- 30 5. The low-energy-diet according to any of the preceding claims, wherein the diet
comprises the protein source in an amount of from 60 g protein to 75 g protein.

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6. The low-energy-diet according to any of the preceding claims, wherein the diet comprises the carbohydrate source in an amount of from 80 g carbohydrate to 110 g carbohydrate.
- 5 7. The low-energy-diet according to any of the preceding claims, wherein at least a part of the carbohydrate source is selected from dihydroxy acetone phosphate and/or pyruvate.
- 10 8. The low-energy-diet according to claim 7, wherein the diet comprises dihydroxy acetone phosphate and/or pyruvate in an amount sufficient to increase the energy expenditure.
- 15 9. The low-energy-diet according to claim 7 or 8, wherein the diet comprises dihydroxy acetone phosphate and/or pyruvate in an amount sufficient to increase satiety.
10. The low-energy-diet according to claim 7, 8 or 9, wherein the diet comprises dihydroxy acetone phosphate in an amount of from 5 g to 15 g.
- 20 11. The low-energy-diet according to claim 7, 8, 9 or 10, wherein the diet comprises pyruvate in an amount of from 5 g to 20 g.
12. The low-energy-diet according to claim 11, wherein the pyruvate is in the form of sodium pyruvate and/or calcium pyruvate.
- 25 13. The low-energy-diet according to any of the preceding claims, wherein at least 3 g of the fat source is a fat source capable of increasing the energy expenditure.
- 30 14. The low-energy-diet according to any of the preceding claims, wherein the medium chain triglycerides are selected from C6 triglycerides, C8 triglycerides and C10 triglycerides.
- 35 15. The low-energy-diet according to any of the preceding claims, wherein at least 3 g of the fat source is fish oil.

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16. The low-energy-diet according to any of the preceding claims, wherein the diet comprises pH-regulating agent in an amount sufficient to reduce protein degradation.

5 17. The low-energy-diet according to claim 16, wherein the diet comprises as the pH-regulating agent bicarbonate in an amount sufficient to reduce protein degradation.

10 18. The low-energy-diet according to claim 16, wherein the diet comprises bicarbonate in an amount of from 50 mmol/d to 70mmol/d.

19. The low-energy-diet according to any of the preceding claims, wherein diet comprises iron in an amount sufficient to modulate the basal metabolic rate.

15 20. The low-energy-diet according to claim 19, wherein the diet comprises iron in an amount sufficient to prevent reduction in the basal metabolic rate.

21. The low-energy-diet according to claim 19 or 20, wherein the diet comprises iron in an amount of from 20 mg/d to 30 mg/d.

20 22. The low-energy-diet according to any of the preceding claims, wherein the diet further comprises dietary fibres.

25 23. The low-energy-diet according to claim 22, wherein the dietary fibres are selected from barley fibres, sugar beat fibres and oat fibres.

24. The low-energy-diet according to any of the preceding claims, wherein the diet further comprises magnesium.

30 25. The low-energy-diet according to claim 24, wherein the magnesium is added as MgCl.

35 26. The low-energy-diet according to any of the preceding claims, wherein the diet further comprises ursodeoxy cholic acid.

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27. The low-energy-diet according to any of the preceding claims, wherein the diet is in the form of powder.

5 28. The low-energy-diet according to claim 27, wherein the powder is capable of being suspended or solved in liquid, such as liquid selected from water and milk.

29. The low-energy-diet according to any of the preceding claims 1-28, wherein the diet is in the form of ready-to-drink product.

10 30. The low-energy-diet according to any of the preceding claims 1-28, wherein the diet is in the form of bar product.

15 31. The low-energy-diet according to any of the preceding claims, wherein the diet is suited for the main or sole nutrition daily, said diet being divided into two or more portions per day.

20 32. The low-energy-diet according to claim 31, wherein the diet is packed in a package intended for being able to cover the total nourishment requirement for a defined period of time.

33. A method for treating overweight comprising administering to an individual in need thereof an effective amount of a low-energy-diet as defined in any of the claims 1-31 as the main or sole nutrition daily.

25 34. Use of ingredients being sources of

protein in an amount of from 50 g to 80 g per day,

carbohydrate in an amount of from 70 g to 120 g per day,

fat 5-20 g per day, including at least 3 g middle chain triglycerides per day,

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and optionally minerals and pH-regulating agents, wherein one or more of the ingredient(s) has effect on at least two of the following mechanisms

the basal metabolic rate, and/or

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the protein metabolism, and /or

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the energy expenditure,

when the low-energy-diet is administered as the main or sole nutrition, and
wherein the diet has an energy content in the range of from 600 kcal/d to 1200
kcal/d,

for the production of a low-energy-diet for administration as the main or sole nu-
trition.

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35. The use according to claim 34, wherein the ingredients are as defined in any of
claims 1-28.

36. The use according to claim 34 or 35, wherein the diet is in the form of a powder
or a ready-to-drink product or a bar product.

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Abstract

5 The present invention relates to a low-energy diet (LED) having effect on the basal metabolic rate, the protein metabolism and/or the energy expenditure, such as a low-energy-diet comprising Carbohydrate: 70-120 g, Protein: 50-80 g, Fat 5-20 g, including medium chain triglycerides, and Iron: 20-30 mg/d, wherein the carbohydrate source and/or the fat source may increase the energy expenditure.

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